



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/665,725

09/16/2003

Siau-Way Liew

3155/119

4659

75059

7590

04/29/2010

Sunstein Kann Murphy & Timbers LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

04/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,725	Applicant(s) LIEW ET AL.	
	Examiner JOHN F. RAMIREZ	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9,10,12-55,89-99,101-184 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,9,10,14-55 and 106-115,131-172,174-184 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,13,89-99,101-105,116-130 and 173 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/30/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/01/10 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 12, 89-91, 93-103, 118-119, 124-130 and 173 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 89-91, 93-99, 101-103, 118-119, 127-130 and 173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (US 6,442,287) in view of Grunkin et al. (US 5,915,036) of record.

Art Unit: 3737

Jiang discloses an automated method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including population data such as age of the patient, were used to determine the strength of bone and thus the likelihood of risk of future fracture. One of the variables is the 3D orientation of the trabecular network. Since 3D trabecular orientation is invasive or destructive, Jiang uses texture orientation to estimate the 3D structural information of the 3D orientation of the trabecular network from a non invasive and non destructive projection radiograph (two-dimensional image). This extracted structural features is then further used to generate texture information such as the Minkowski dimension (fractal dimension) and the volumetric bone mass density (abstract, col. 6 line 27-65, col. 17 line 15-47, col. 20 line 22-42, see figs. 1A and 22). However, Jiang et al. does not explicitly disclose combining at least two parameters from the group consisting of total area, trabecular perimeter, node count (N), segment count (S), node-to-free-end segment count (NF), and mean distance transform values for each connected skeleton.

In the same field of endeavor, Grunkin et al. teach a method for analyzing bone wherein the strength of the bone is estimated and thus the likelihood of risk of future fracture (see abstract, col. 1, lines 3-7, col. 4, lines 35-63). Multiple variables, including micro-structural parameters (col. 4, lines 5-14), macro-anatomical parameters and biomechanical parameters (see claim 33, col. 10, lines 25-29) of a vertebrae were analyzed and evaluated based on x-ray imaging information (col. 1, lines 44-49, col. 14, lines 21-41) relating to the trabecular structure to determine the strength of bone (col. 2, lines 1-36).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Jiang et al., with the above discussed enhancements would have been considered obvious because such modifications would have provided a more reliable estimation of the bone quality (col. 3, lines 22-24).

Claims 116-117, 120-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumagai (US 6,306,822 B 1) in view of Jiang et al. (US 6,442,287) in view of Grunkin et al. as claimed above in claim 12.

Kumagai discloses a method for treating or preventing any condition associated with bone loss through administering an agent to the subject. The bone quality measurement is first measured on day 0, before treatment begins, then again on day 45 and day 90. The bone quality is then compared, showing the effectiveness of each of the agents on remodeling the bone (fig. 5, col. 13 line 60-63). Kumagai does not disclose the specifics on how they measure the bone density. It would be obvious to one skilled in the art at the time of the invention to use any method that is well known in the art such as the method that is disclosed in Jiang et al. in view of Grunkin et al. as explained above.

Claims 92, and 104-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (US 6,442,287) in further view of Grunkin et al. as claimed above in claim 12.

Art Unit: 3737

In regards to **claims 104-105**, Jiang et al. disclose an automated method for analyzing bone wherein the strength of the bone is estimated and analyzed (see abstract). Jiang et al. do not disclose the total bone factor as claimed in claim 13, and converting the 2D pattern into a 4D pattern as claimed in claims 104, 105 and 113.

It would have been an obvious design choice for one of ordinary skill in the art at the time for the invention to have expected Jiang et al. method and applicant's invention, to perform equally well. Furthermore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the method disclosed by Jiang et al. in view of Grunkin et al. as discussed above in claim 12, to obtain the invention as specified in claims 104-105 and 113 because such a modification would have considered a mere design consideration which fails to patentably distinguish over the prior art of Jiang et al in view of Grunkin et al.

In regards to **claim 92**, it would have been prima facie obvious to one of ordinary skill in the art to have modified the method disclosed by Jiang et al. in view of Grunkin et al. as discussed above in claim 12, by using the image of a horse to analyze bone mass and structure for the assessment of bone strength and/or osteoporosis since it is well known that osteoporosis can occur in both human and animal subjects.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

Art Unit: 3737

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John F Ramirez/
Examiner, Art Unit 3737